IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* JOHN N. KRAMER, D.D.S., Relator,	§	
	§	CIVIL ACTION NO. 1:18-cv-373-DRC
v.	§	
	§	Judge Douglas R. Cole
ROBERT A. DOYLE, D.M.D., *et al.,* Defendants.	§	

DEFENDANTS ROBERT A. DOYLE, D.M.D., CDC CALCUTTA, LLC, CDC DENNISON, LLC, CDC MARTINS FERRY, LLC, CDC NEWCOMERSTOWN, LLC, CDC SHADYSIDE, LLC, CDC STEUBENVILLE, LLC AND CDC CHAMPION HEIGHTS, LLC'S REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

Defendants Robert A. Doyle, D.M.D., CDC Calcutta, LLC, CDC Dennison, LLC, CDC Martins Ferry, LLC, CDC Newcomerstown, LLC, CDC Shadyside, LLC, CDC Steubenville, LLC, and CDC Champion Heights, LLC (collectively, the preceding seven entities are referred to as the "CDC Defendants"), hereby file this reply in support of their motion to dismiss this case with prejudice under Federal Rule of Civil Procedure 12(b)(6) [Doc. 48] because relator has failed to state a claim upon which relief may be granted.[1]

Relator's response to the motion filed by Doyle and the CDC Defendants [Doc. 54] also serves as his response to the separate motion to dismiss filed by NADG [Doc. 49]. In addition to mischaracterizing and or conflating the arguments of the two defendant groups, relator's response inaccurately characterizes the allegations in his third amended complaint [Doc. 37],[2] relies on unsupported inferences from those allegations, and misapplies the relevant law. Once these issues are stripped away, relator's arguments collapse – as do his claims.

[1] For purposes of this motion, of course, the allegations in the third amended complaint must be accepted as true. Doyle and the CDC Defendants emphasize that they do not admit any of the allegations in any of relator's complaints.

[2] Because the pending motion to dismiss concerns only the complaint's current iteration, all further references to the complaint relate to the pending third amended complaint, Doc. 37.

I. RELATOR MISSTATES THE PLEADING STANDARDS UNDER RULE 9(B)

Overall, relator's response understates the pleading standard for False Claims Act ("FCA") cases under Federal Rule of Civil Procedure 9(b). For example, relator correctly states that this Court must "draw all reasonable inferences in favor of the complaint." Doc. 54, Memorandum in Response to Motion to Dismiss at PAGEID 623, *quoting Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 876 (6th Cir. 2006). But relator ignores the fact that while reasonable factual inferences are credited, courts "do[] not apply this presumption of truth to conclusory or legal assertions." *Binno v. Am. Bar Ass'n*, 826 F.3d 338, 345-46 (6th Cir. 2016) (citation omitted). Further, as relator's own caselaw explains, it is the allegations in the complaint, not the arguments in his brief, that inform this Court's analysis of the Rule 9(b) standards. *See U.S. ex rel. Prather v. Brookdale Senior Living Ctr.*, 838 F.3d 750, 762 (6th Cir. 2016) (noting that relator's suggested theory of liability in brief did not match allegations in complaint for purposes of Rule 9(b)'s particularity requirement). Relator's response [Doc. 54] goes beyond reasonable inferences. It includes arbitrary theories, unsupported conclusions, and interpretations of the allegations in the complaint in an attempt to bolster his arguments that those allegations are sufficient under Rule 9(b). These theories, conclusions, interpretations, and legal arguments are not accorded any presumption of truth.

In discussing the pleading requirements, relator relies on the argument that a complex, widespread scheme may be alleged by pleading a single representative example. *See* Doc. 54 at PAGEID 615 (citing *Prather*, 838 F.3d at 768). Relator ignores the further clarification, on the same page of the same case he cites, that "[a]lthough the relator does not need to identify every false claim submitted for payment, [s]he must identify with specificity *characteristic examples* of the class of all claims covered by the fraudulent scheme." *Prather*, 838 F.3d at 768 (internal quotations omitted, emphasis added). Here, relator has only six examples, and they are not characteristic of the universe of patients. Of the six patients in the complaint, five were

previously treated at CDC Martins Ferry, the town in which relator's dental practice is located; one was treated at CDC Steubenville. None were treated at any other CDC location. For this reason alone, relator's examples are not the type of 'characteristic examples' demanded by *Prather* to support "allegations of a complex and far-reaching fraudulent scheme." *Id; see also U.S. ex rel. Bledsoe v. Cmty. Health Sys. ("Bledsoe II")*, 501 F.3d 493, 510-11 (6th Cir. 2007) (in order to proceed to discovery, "[t]he examples of false claims pled with specificity should, in all material respects, including general time frame, substantive content, and relation to the allegedly fraudulent scheme, be such that a materially similar set of claims could have been produced with a reasonable probability from the total pool of all claims"). And despite relator's argument to the contrary, the Sixth Circuit has "conclude[d] that the concept of a false or fraudulent scheme should be construed as narrowly as is necessary to protect the policies promoted by Rule 9(b)." *U.S. ex rel. Snapp, Inc. v. Ford Motor Co.,* 532 F.3d 496, 508 (6th Cir. 2008) (internal quotation omitted).

II. THE COMPLAINT FAILS TO SATISFY RULE 9(B) BECAUSE IT LACKS PARTICULARLIZED ALLEGATIONS AS TO DR. DOYLE AND AS TO FIVE OF THE SEVEN CDC DEFENDANTS

First, as to Dr. Doyle personally and five of the seven CDC Defendants, relator has not sufficiently alleged their involvement in any of the supposed "false claims." Relator does not dispute that he has no knowledge of the treatment of patients or billing to Medicaid at CDC Calcutta, CDC Dennison, CDC Newcomerstown, CDC Shadyside, or CDC Champion Heights. Nor does he claim that Dr. Doyle treated any of the patients at any CDC Defendant (or elsewhere) or that he prepared, reviewed, or submitted the bills presented to Medicaid for their treatment. These flaws are fatal to the claims against these six defendants.[3]

[3] Relator claims that Dr. Doyle and the CDC Defendants admit that his allegations are sufficient to state a claim against CDC Steubenville and CDC Martins Ferry, the two locations where the patients identified in the complaint were treated. Doc. 54 at PAGEID 614, n.1. While defendants do not dispute that the allegations against these two defendants are sufficiently particular, relator has still failed to state a claim against **any** of the CDC Defendants for

Regarding Dr. Doyle, although relator attempts to add to these allegations in his response to the motion to dismiss, the complaint (which is the relevant document) alleges only that Dr. Doyle owned, controlled, and mentored the CDC Defendants; that he "directed" policies and procedures at the CDC clinics; that he is registered to provide services at all CDC locations; and that he was responsible for certain financial goals for each CDC Defendant. Doc. 37 at PAGEID 448-49. None of these allegations supports FCA liability as to Dr. Doyle personally. First, the simple recitation of ownership, control, and mentorship is far from providing the "who, what, where, when, and why" of the alleged fraudulent scheme. For example, relator alleges that Dr. Doyle "directed" procedures at the clinics but does not specify which procedures, nor how this vague "direction" of procedures and practices is sufficient to allow this Court to infer that Doyle required sixteen other dental professionals to commit a very specific type of fraud involving root canals and tooth extractions.

Relator next argues that Doyle's liability is based upon "reckless disregard" because he "fail[ed] to make simple inquiries which would alert [him] to the false claims." Doc. 54 at PAGEID 644 n.10. But the complaint does not include any allegation of reckless disregard or failure to inquire. *Id.* (citing paragraphs in complaint relevant to Doyle). Even if it did, relator has not identified what "simple inquiries" Doyle should have made or why he should have known to make them. Does relator contend that Doyle should review every x-ray, test, and bill at all seven CDC locations to make sure that all bills have been properly prepared? Or does relator rather suggest that there were red flags indicating issues at the CDC offices that Doyle chose to ignore, such as failed audits, sharply increased revenues with no logical explanation, or recoupment requests received?

Relator's argument that he has plead an FCA claim against Dr. Doyle based on the daily

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the reasons discussed in the remainder of this brief and in defendants' memorandum in support of their motion to dismiss.

financial or production goals for the CDC offices is also unavailing. First, again, relator's response misstates his own allegations. Relator's response to the motion to dismiss claims that these "financial goals are set for all the CDC offices by [Dr. Doyle]." Doc. 54 at PAGEID 621. But the complaint says that Dr. Doyle does *not* set the financial goals for the CDC offices, but rather that the "employees take turns setting the production goals for the day." Doc. 37 at PAGEID 490. The complaint contains no allegation that Dr. Doyle requires a certain minimum production goal to be set by the employees or even that he requires them to relate that day's goal to him, let alone that *Dr. Doyle* "purposefully set monetary production goals far higher than could be reached by regular medically necessary treatment of patients in the area." Doc. 54 at PAGEID 621.

Second, relator asserts that these financial goals can be met only if fraud is committed, comparing a reported CDC goal of $25000 per day for one office[4] to his own estimation that a "good day" for a solo dentist would be $5000 per day.[5] Doc. 54 at PAGEID 621; Doc. 37 at PAGEID 491. Putting aside potential differences in the percentage of patients who are Medicaid beneficiaries versus privately insured or cash-paying patients and the office hours of the various practices, seventeen dentists work at one or more CDC locations. Doc. 37 at PAGEID 449. Multiple dentists working with a large team of other dental professionals can obviously bill more than a single dentist, and a "good day" for one dentist might be an "average" or "bad" day for another. Relator himself admits in the complaint that "EFDAs are used extensively" at all of the CDC locations, increasing the number of patients that can be served.[6] Doc. 37 at PAGEID 491.

[4] Relator does not allege that these goals related to Medicaid patients specifically, rather than to all patients. Obviously, dentists are not limited by Medicaid rules or reimbursement rates when they are not treating Medicaid patients.

[5] Relator does not explain the basis for his $5000 per day number, other than his own experience as a dentist practicing alone in one of the seven towns in which CDC is located.

[6] An "EFDA" is an Expanded Function Dental Auxiliary. In Ohio, these professionals are permitted to perform "advanced remediable intra-oral dental tasks and/or procedures" including placing sealants and amalgam or composite fillings. Ohio Admin. Code 4715-11-04.

Finally, relator's theory is that the financial goals set in the CDC offices force dentists and other professionals to commit Medicaid fraud because there is no other way to reach the daily production goals through "regular medically necessary" treatment of patients. Doc. 54 at PAGEID 621. Yet the complaint admits that "not much happens" when an office fails to meet the daily goals, except that they might "hear about it" on a phone call. Doc. 37 at PAGEID 491. If production goals are regularly met, employees get a bonus of $500 per quarter, which "would not be atypical in the industry." *Id.* The mere existence of production goals that are not required to be met, do not result in negative repercussions if they are not met, and reward employees with a "not atypical" bonus if they *are* met does not support a conclusion that those who work at a CDC location – including professionals with their licenses at stake – are cowed into fraudulent billing practices by these daily goals.

With respect to the five non-treating CDC Defendants, relator claims that because he has alleged a "widespread and complex scheme," he need not identify any specific instances of fraud at any of those five practices. Doc. 54 at PAGEID 644. Relator's assertion is contrary to law. *See Bledsoe II*, 501 F.3d at 510-11 (examples of fraudulent scheme should be similar enough in all material respects that a random draw would have a reasonable probability of producing a similar set of claims). Relator asserts that seven separate CDC entities are participating in the same "scheme" to defraud Medicare by performing root canals on teeth instead of extractions. Yet the six examples in the complaint come from only two of these entities, and even then are not evenly split between them: five of the six "example" patients (patients one, three, five, six, and seven) were treated at CDC Martins Ferry; only patient two was treated at a different location, CDC Steubenville. Doc. 37 at PAGEIDS 470, 483, 485, 496, 500, 504. So relator's examples are not materially similar to a random sample taken from all seven CDC Defendants. Relator cannot remediate his failure to make particularized allegations against these five other

entities simply by airily declaring that he does not have to allege facts regarding those defendants because he has alleged a "scheme."

III. THE COMPLAINT DOES NOT SUFFICIENTLY PLEAD LACK OF MEDICAL NECESSITY

The second reason the complaint should be dismissed, as to all defendants, is that its allegations regarding medical necessity amount to no more than a difference of professional opinion regarding treatment plans. But it is not fraud for one dentist to examine a patient, determine that a root canal is needed, and then perform and submit a claim for payment for that root canal just because another dentist states that he would have extracted the tooth on which the root canal was performed. Relator incorrectly argues that a difference in medical opinion may suffice to state a claim under the FCA. Doc. 54 at PAGEID 634-35. The cases cited for this proposition are criminal cases in which courts concluded that the false statements that resulted in health care fraud convictions were not professional medical opinions, but instead were either a) statements of fact or b) opinions not legitimately held.

For example, in *U.S. v. Paulus*, the Sixth Circuit affirmed the conviction of a cardiologist for health care fraud because his descriptions of arterial blockage were statements of fact, not opinions. 894 F.3d 267, 275 (6th Cir. 2018). The court went on to explain that in order to make a false statement, the speaker must have made a statement 'capable of confirmation or contradiction.'" *Id.* (*quoting U.S. v. Kurlemann*, 736 F.3d 439, 445 (6th Cir. 2013)). The Court continued:

> Ordinarily, facts are the only item that fits in this category; opinions—when given honestly—are almost never false. See, e.g., Restatement (Second) of Torts §§ 538A, 539; *Gertz v. Robert Welch, Inc.,* 418 U.S. 323, 339, 94 S. Ct. 2997, 41 L. Ed. 2d 789 (1974) ("[T]here is no such thing as a false idea."). But opinions are not, and have never been, completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion.

Id. Similarly, in *U.S. v. Bertram*, the court affirmed defendants' convictions despite their

argument that they could have reasonably believed the lab tests in question were medically necessary, because this argument was contrary to the evidence at trial. 900 F.3d 743, 750 (6th Cir. 2018). In other words, the opinions at issue in *Bertram* were fraudulent only because they were not honestly held. *See also U.S. v. Chalhoub*, No. 6:16-cr-00023-GFVT-HAI, 2018 WL 6709715, at *2 (E.D. Ky. Dec. 20, 2018) (finding evidence supported jury's finding that doctor's actions were part of a knowing and willful scheme to defraud insurance companies and not based on good faith medical judgment). There is no allegation in the complaint, and relator does not even attempt to identify one, that false statements of *fact* were made on a submitted claim or that any CDC dentist did not honestly hold the opinion that one or more root canals was the appropriate treatment for each of the six patients.

Many courts have recognized that legitimately held medical opinions are not fraudulent in the context of a civil FCA case simply because another provider disagrees with them. In other words, courts "would not find a cognizable claim under the FCA if the [relator] simply disagreed with a reasonable medical or care treatment administered by the Defendant." *U.S. v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000).[7] *See also U.S. v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019) ("[a] properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong"); *U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) ("the FCA requires a statement known to be false, which means a lie is actionable but not an error"); *U.S. ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005)("the False Claims Act should not be used to call into question a health care provider's judgment regarding a specific course of treatment").

[7] Relator dismisses this explanation as dicta because the *NHC Healthcare* court did not dismiss the complaint in question. The quoted language is part of the court's discussion of the standard to be applied in FCA cases.

None of the complaint's allegations rise above the type of differing professional opinions that are not actionable under the FCA. There are six example patients in the complaint, each of which had one or more root canals at a CDC location.[8] Relator admits that root canals are proper when a patient has pain, trauma, or an infection. Doc. 54 at PAGEID 617. He then alleges that "some" patients reported no signs or symptoms of an infection. Doc. 54 at PAGEID 618. But Medicaid does not require a patient to *report signs or symptoms* of an infection; instead, it requires the presence of an infection – which can exist even in the absence of symptoms. Additionally, relator says that medical records for "numerous" patients "failed to document that clinical symptoms for those root canals were satisfied." Doc. 54 at PAGEID 618. In addition to the fact that Medicaid does not require the presence of symptoms for every root canal, the complaint's only support for this "lack of documentation" claim is that relator has seen some of the medical records pertaining to patients one and three. Doc. 37 at PAGEID 475 (patient one obtained "medical records" from CDC, but no allegation that patient obtained or asked for complete medical records); *id.* at PAGEID 486 (patient three only received x-rays from CDC). Relator has not seen any patient's complete medical record; for example, he does not allege that he saw any notes by the dentist that would document such symptoms if they did exist. For patient one, relator admits he has not seen x-rays performed by CDC; for patient three, he admits that he has only seen x-rays. Doc. 37 at PAGEID 475, 486. Relator merely speculates that the documentation required by Medicaid was not present for any of the patients, let alone for all six patients.

The complaint makes the following specific allegations about the six individual patients in question:

- **Patient one** is not directly addressed in relator's response brief, Doc. 54, but relator does

[8] Relator's complaint discusses eight individuals, but one of them was not a Medicaid recipient and another had root canals recommended, but never performed. Patients for whom no claim was submitted to Medicaid cannot support a claim under the FCA, so only the other six patients are discussed here. The non-included patients are patients four and eight. Doc. 54 at PAGEID 619.

note that he is in possession of the names of the treating dentists and other CDC dental professionals involved in his care.[9] Doc. 54 at PAGEID 639 n.9. Patient one is the only patient in the complaint for whom relator has properly pled that claims were made to the government for payment by identifying the dates, codes, and payments associated with the work done by CDC Martins Ferry in 2015 and 2016. A review of those claims as listed in paragraph 133 of the complaint [Doc. 37 at PAGEID 481-82] reveals that a crown was requested and paid for by Medicaid for each tooth in question. Like partial dentures after extractions, crowns placed after root canals require preauthorization. Ohio Admin. Code 5160-5-01(F)(1), Appendix A at p. 7. As part of that authorization process, Medicaid reviews the records, x-rays, and photographs (if any) relating to the root canal in question. If Medicaid did not agree both that the root canal was an appropriate choice for the patient and that it was performed competently, it would not have approved the crown (and would have demanded repayment of the previous amounts received by the provider for the root canal). But in patient one's case, relator's own complaint reflects Medicaid's determination that the root canals were appropriate; Medicaid approved a crown for each tooth in question. There can be no false claim associated with root canal therapy when the government – to whom the false claim was supposedly made – has already decided that the root canals were appropriate and medically necessary.

- **Patient two** allegedly received root canals on teeth that were grossly decayed and not appropriate for root canals rather than extraction. Doc. 54 at PAGEID 618. Relator does not allege that no reasonable dentist would have tried to save these front teeth rather than extract them. Doc. 54 at PAGEID 618. Relator acknowledges that crowns were needed

[9] Although the records and names which are in relator's possession have not been shared with defense counsel, relator has not alleged that Dr. Doyle one of the treating dentists for patient one. It is unclear why the names of the treating dentists for patient one could not have been included in the complaint (even by initials), nor why any production of them would need to be *in camera*.

for these teeth after the root canals but assumes, without basis, that crowns were denied by Medicaid.[10] Doc. 37 at PAGEID 483-84. Meanwhile, relator maintains that the root canals were improper, partially because the patient said that she wanted the teeth extracted. Doc. 54 at PAGEID 636. But while patient preference should of course be considered, it cannot serve as the sole reason for choosing a treatment plan that will be billed to Medicaid. In fact, relator makes this exact point in the other direction only *two sentences later* by saying, "root canals are not covered by Medicaid when provided due to patient desire in the absence of satisfaction of coverage requirements." *Id.* Of course, the same is true for extractions.[11]

- Relator refers to **patient three** as an "alarming example" because he received six root canals in the absence of reported pain or trauma. But relator does not make any allegations denying the existence of infection(s) in patient three. The absence of pain or trauma alone does not support an argument that the root canals were unwarranted. Doc. 54 at PAGEID 618.
- **Patient five** received root canals despite a lack of reported pain, trauma, or "signs or symptoms of infection." As noted above, none of these are required for a root canal to be performed and paid for by Medicaid if an infection in fact exists. Doc. 54 at PAGEID 618.
- Like patient five, **patient six** received root canals despite a lack of reported pain, trauma, or "signs or symptoms of infection." As noted above, none of these are required for a root

[10] An equally valid inference from the lack of crowns on these teeth would be that patient two did not want to go back to CDC to have crowns placed because she was unhappy that the teeth had not been extracted.

[11] Relator's argument about the relevance of patient desires is apparently based on one sentence in the motion to dismiss (Doc. 48 at PAGEID 558): "The CDC dentists sometimes perform root canals in an attempt to allow patients to maintain their own teeth as long as and to the extent possible." Relator misinterprets the connotation of "allow" in this sentence; it was intended to reflect the fact that most dentists would agree that a person's natural teeth are preferable to implants or dentures for a variety of health reasons, just as treatment of an ingrown toenail is preferable to removal of a toe. Of course, patient preference is one of the many factors to consider when creating a dental treatment plan, as relator's complaint recognizes. *See, e.g.,* Doc. 37 at PAGEID 483 (arguing that root canals should not have been performed because patient requested extraction).

canal to be performed and paid for by Medicaid if an infection in fact exists. Doc. 54 at PAGEID 618.

- **Patient seven** received two root canals, but relator's opinion is that one of them was unnecessary because there was no sign of infection in that tooth five days later. Relator admits that the radiolucent lesion he did not see is not always present five days after a root canal but says only that it "typically" is present. More importantly, patient seven reported pain. Root canals are appropriate to treat pain even in the absence of an infection, as relator himself admits. Doc. 54 at PAGEID 619. Even more egregiously, relator claims that "CDC ignored what its own x-ray showed." Doc. 54, PAGEID 635.[12] But relator has never seen any CDC x-ray for patient seven. The x-ray in the complaint that does not show a translucency "typically" seen five days after a tooth infection was taken by relator, not CDC.

Relator's theory is that CDC chose to perform root canals rather than extractions on these six patients because Medicaid pays more for a dentist to perform a root canal than an extraction.[13] Yet relator's analysis of this "financial incentive" doesn't "count" the reimbursement for a partial denture as an incentive to dentists to perform extractions[14] because partial dentures require pre-authorization that "might not be granted." Relator has not indicated the percentage of pre-authorization requests for partial dentures that are granted or denied post-extraction. Without this information, relator cannot say that root canals are always or usually more profitable than extractions, meaning his conclusions

[12] Relator's complaint more correctly states this inference as "Dr. Kramer can only *conclude* that Complete Dental Care purposely ignored what any of its own x-rays *would have shown.*" Doc. 37 at PAGEID 505. While more correct than the phrasing of the response, Dr. Kramer's conclusion about what an x-ray would or would not have shown is a statement of opinion that is not entitled to a presumption of truth.

[13] Relator does not account for the fact that a root canal both takes longer to perform than a simple extraction and requires the dentist to use various materials that are not needed for an extraction.

[14] If the reimbursements are added together, extraction combined with a partial denture results in a higher payment from Medicaid than a root canal. Medicaid does not pay for most crowns after root canals, other than for the teeth that are located between the two canines in the front of the mouth (such as the teeth discussed in regard to patient two). Crowns that Medicaid does pay for also provide pre-authorization, which is provided after Medicaid reviews the records to ensure that the root canal was both properly performed and an appropriate treatment.

about financial incentives cannot be credited.

IV. RELATOR HAS NOT SUFFICIENTLY PLEAD A CLAIM FOR FALSE STATEMENTS MADE IN MEDICAL RECORDS

Finally, Relator's second cause of action for false statements under 31 U.S.C. § 3729(a)(1)(B) should also be dismissed. Relator admits that this cause of action is based on statements from two patients (patients six and seven) that non-dentists performed functions that relator says they were not allowed to perform. Other than these two statements, relator does not allege any basis for claiming that false statements were made to Medicaid; he has no knowledge (nor would the patients in question) that bills were ever submitted requesting payment for these root canals. There are no allegations about the name or position of the person who did the work in question, which relator states was "procedures outside of the scope of their practice." Doc. 54 at PAGEID 620. "Scope of practice" varies depending on whether the person in question is a second dentist, a dental hygienist, an EFDA, or another professional. For example, under Ohio law, an EFDA is permitted to do a range of tasks for placing fillings in teeth, including using a drill to shape and even out the filling so that it fits the patient's mouth correctly and does not affect their bite or cause pain.[15] Ohio Admin. Code 4715-11-04. Fillings are routinely performed after a root canal during the same visit. Without any details about the work performed on patients six and seven, the person or persons who performed it, and any bill that was submitted, no false claim can be inferred.

Relator's implied certification theory states that the bills for these claims, as submitted to Medicaid, were false because they claimed that a dentist performed the entire procedure in question. But no bill submitted to the government is specifically identified. In fact, relator does not know whether a claim was submitted at all. And without details about at least one false claim that was actually submitted to the government, relator's cause of action for making false statements in a claim

[15] Drilling is used for composite fillings, but not for amalgam fillings. Medicaid only covers the cost of amalgam fillings but does not prevent dentists from using the higher cost composite fillings for the same rate.

for payment fails. *See U.S. ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 446 (6th Cir. 2008) ("plaintiff may not describe an alleged fraudulent billing scheme in detail but then allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the government") (internal quotation omitted); *Sanderson*, 447 F.3d at 877-78 (affirming dismissal when complaint did not identify a specific submitted claim by number, date, or other method).

Moreover, relator has not plead that the implied certification that all work was performed by dentists (in the bills he guesses were submitted) was material. While his brief argues that Medicaid would consider any work performed by a non-dentist to be material, he avoids addressing the requirement that materiality is a "demanding standard" by simply repeating the definition of materiality. Doc. 54 at PAGEID 645; *see Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016) (remanding to district court for determination of materiality of use of unqualified staff). Further, despite relator's conclusion in his briefing that use of a non-dentist would be material in this case, Doc. 54 at PAGEID 646-47, the only allegation he points to in the complaint to support materiality is a recitation of a statute requiring that services must be within the provider's scope of practice. *Id.*, Doc. 37 at PAGEID 463 (discussing Medicaid requirements). One paragraph reciting statutory language does not meet the "demanding standard" to properly allege materiality; a relator must allege not only *what* the government would have done (i.e., refuse to pay for the services) in the absence of the implied certification, but *why*. *See id.* at 2002-03 (holding that identifying a condition of payment is not dispositive of materiality); *see also U.S. ex rel. Dresser v. Qualium Corp.*, No. 5:12-CV-01745-BLF, 2016 WL 3880763, at *6 (N.D. Cal. July 18, 2016) (relator did not sufficiently plead materiality when complaint stated that government would not have paid claims if it had known defendants were using unqualified personnel but failed to explain why).

V. FURTHER AMENDMENT SHOULD NOT BE ALLOWED

Finally, relator asks this Court not to dismiss his complaint with prejudice, but to allow him to replead for a fifth time, claiming he has "significant additional corroborating evidentiary details" of wrongdoing. Doc. 54 at PAGEID 650. Respectfully, relator has had four chances to plead his claims. His latest amendment was made in response to almost fifty pages of briefing by defendants in support of motions to dismiss the second amended complaint. If relator had the ability to better plead his case, he could (and should) have done so by now. For this reason, Doyle and the CDC Defendants request that relator's request to amend his complaint be denied and that this case be dismissed with prejudice.

February 6, 2020

/s/ Patrick C. Haney
Patrick C. Haney
Ohio Bar No. 0092333
Patrick.Haney@ChandraLaw.com
TRIAL COUNSEL
THE CHANDRA LAW FIRM, LLC
The Chandra Law Building
1265 W. 6th St., Suite 400
Cleveland, Ohio 44113-1326
Phone: 216-578-1700
Fax: 216-578-1800

/s/ Elizabeth K. Stepp
Elizabeth K. Stepp *(pro hac vice)*
Texas State Bar No. 00788467
eks@federal-lawyer.com
Lynette S. Byrd *(pro hac vice)*
Texas State Bar No. 24047126
lsb@federal-lawyer.com
OBERHEIDEN P.C.
5728 LBJ Freeway, Suite 250
Dallas, Texas 75240
(214) 334-7648 (Telephone)
(972) 559-3365 (Facsimile)
ATTORNEYS FOR DEFENDANTS ROBERT A. DOYLE, D.M.D., CDC CALCUTTA, LLC, CDC DENNISON, LLC, CDC MARTINS FERRY, LLC, CDC NEWCOMERSTOWN, LLC, CDC SHADYSIDE, LLC, CDC STEUBENVILLE, LLC AND CDC CHAMPION HEIGHTS, LLC

CERTIFICATE OF SERVICE

I hereby certify that on February 6, 2020, a true and correct copy of the above and foregoing document was served on all counsel of record through the Court's electronic filing system.

/s/ Elizabeth K. Stepp
Elizabeth K. Stepp